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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas H. Ryan, President
Homecare Concepts, Inc.
1095 Route 110
Farmingdale, NY 11735-4819

January 29, 1999

Ref: NYK-1999-27

Dear Mr. Ryan:

During an inspection of your medical oxygen filling facility located in Farmingdale, New York conducted December 2 through 23, 1998, our investigator documented deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your oxygen drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to, the following:

1. Failure to adequately test incoming liquid oxygen in large cryogenic vessels for both identity and strength prior to filling cryogenic home vessels. (Acceptable methods of testing incoming liquid oxygen are outlined in the February 1989, Compressed Medical Gases Guideline.) [21 CFR 211.165(a)]

2. Failure to establish and follow written procedures for performing heat of compression checks during the filling of high-pressure cylinders. These checks should be documented at the time of performance. [21 CFR 211.100(a) and (b)]

3. Failure to adjust fill pressures to assure that high-pressure cylinders are filled to their indicated service pressures at 70°F. [21 CFR 211.101(a)]

4. Failure to perform the required USP odor test on each filled high-pressure cylinder tested prior to release of the lot for distribution. [21 CFR 211.165(a)]

5. Failure to include in the batch production records for oxygen in high-pressure cylinders a distinctive lot number for each manifold filling sequence during a day's production. According to current good manufacturing practice, each manifold filling sequence, each uninterrupted filling sequence, and each cryogenic vessel filled is considered a new lot and is required to be assigned a new lot number. As such, it is unacceptable to document a single lot number in the batch record for more than one manifold filling sequence. [21 CFR 211.188]

6. Failure to properly calibrate the oxygen analyzer used for the assay of medical oxygen in that you did not use suitable standard reference oxygen. Your calibration oxygen was labeled as a secondary standard. A certificate of analysis should accompany each calibration standard. Calibration standards can not be medical or industrial grade, and should be obtained from a manufacturer of standard gases. [21 CFR 211.160(b)(4)]

7. Failure to document the daily and periodic calibrations of vacuum gauges used during the evacuation of high-pressure cylinders and the periodic calibrations of pressure gauges used in filling high-pressure cylinders and cryogenic home vessels. Gauges are required to be periodically calibrated to standards established by the National Institute of Standards and Technology. Further, there was no qualification of the multiple outlet manifold/rack system used to fill high-pressure cylinders to assure that the vacuum and fill pressure are uniform throughout the system. [21 CFR 211.68(a)]

8. Failure to document that each employee involved in the filling of medical oxygen is trained and familiar with the CGMP requirements as they relate to the particular operations that the employee performs. [21 CFR 211.25(a)]

9. Failure to document the receipt and examination of each batch of oxygen labels to assure correctness. Further, the approved master oxygen label attached to the firm's filling SOPs was not the current label in use. [21 CFR 211.122]

In addition, the cryogenic home vessels of liquid oxygen are misbranded within the meaning of Section 502(b)(2) of the Act in that their labeling fails to contain a statement of the net quantity of contents in commonly used units of measure. [21 CFR 201.51]

Neither the above identification of CGMP violations nor the inspectional observations (a copy of the Form FDA 483 is enclosed) presented to you at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drug products so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and injunction.

You should notify this office in writing, within 15 working days after receipt of this letter, of (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which the corrections will be completed; (3) any reason why the corrections have not been completed within the response time; and (4) any documentation necessary to show the corrections have been achieved.

Your reply should be sent to the attention of Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Tel. (718) 340-7000 ext. 5507.

Sincerely,

Brenda J. Holman
District Director

Enclosures: Form FDA 483 dated December 23, 1998
"Fresh Air '98"" A Look at FDA's Medical Gas Requirements